

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 21 SEP 2005

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Applicant's or agent's file reference FEM/MP30966PC	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/GB2004/004360	International filing date (day/month/year) 15.10.2004	Priority date (day/month/year) 15.10.2003	
International Patent Classification (IPC) or national classification and IPC A61B17/128			
Applicant FEMCARE LIMITED et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 13.05.2005		Date of completion of this report 20.09.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Arjona Lopez, G Telephone No. +49 89 2399-	



**INTERNATIONAL PRELIMINARY REPORT
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-9 as originally filed

Claims, Numbers

1-14 as originally filed

Drawings, Sheets

1/5-5/5 received on 26.11.2004 with letter of 22.11.2004

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. 1-13 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-14
	No: Claims	1
Inventive step (IS)	Yes: Claims	2-14
	No: Claims	1
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Re Item IV.

1. The separate inventions are:

- Claims 1-13: An applicator comprising a barrel portion to hold a surgical clip and a handle portion comprising trigger means operable to effect closure of a surgical clip held within said barrel, whereby the trigger is provided with a visual indicator means indicative of the trigger position at which the clip held in the barrel is closed to a half closed position; and

- Claim 14: An applicator comprising a barrel portion having gripping means at a distal end of said barrel and a handle portion comprising trigger means operable to move said gripping means to held an object, whereby the trigger is provided with a visual indicator means indicative of a defined intermediate trigger position comprising a change in surface texture being dimensioned such that the clearance between the trigger means and a main body portion of the handle is minimal.

2. They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

2.1 The common concept linking together the subject-matter of independent claims 1 and 14 is an applicator comprising a barrel portion and a handle portion comprising trigger means operable to interact with an object inside the barrel, whereby the trigger is provided with a visual indicator means indicative of a determinate intermediate trigger position. This common concept is known, see for example documents US-A-5 755 726 or EP-A-1 304 079, the visual indication being provided by the amount of trigger material kept outside the handle (for example half of the trigger).

2.2 Besides, there is no technical relationship between the technical features of independent claims 1 and 14. The subject-matter of claim 1 solves the problem of avoiding over-closure of a surgical clip during passage of an applicator barrel down a cannula, while the subject-matter of claim 14 solves the problem of avoiding that surgical gloves are damaged by being caught between the trigger and the recess in the handle.

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Re Item V.

- 1 The following documents are referred to in this communication:

D1: US-A-5 755 726

D2: EP-A-1 304 079

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Documents D1 and D2 disclose (the references in parentheses applying to these documents): An applicator (D1: 10) comprising a barrel portion (D1: 18; D2: 14) to hold a surgical clip and a handle portion (D1: 12; D2: 12) comprising trigger means (D1: 14; D2: 18) operable to effect closure of a surgical clip held within said barrel, whereby the trigger is provided with a visual indicator means (i.e the amount of trigger material left outside the stationary portion of the handle) indicative of the trigger position at which the clip held in the barrel is closed to a half closed position.
3. The special features of dependent claims 2-13 seems to be new and inventive in the light of the available prior art. The subject-matter of dependent claims 2-4, 10-11, which refers directly to claim 1, has in common the provision of geometrical features in the trigger means in order to provide the above visual indication. Document D1, for example, discloses some kind of visual means (window 24) in the stationary portion of the handle. It does not seem to be any reason why the person skilled in the art would provide said window in the trigger to provide an alternative visual reference.
4. The subject-matter of independent claim 14 is new in the sense of Article 33(2) PCT.
- 4.1 Document D1 discloses (the references in parentheses applying to this document): An applicator (10) comprising a handle portion (12) and a barrel portion (18), the barrel portion having gripping means (20) at a distal end from the handle for gripping an object, the handle portion including trigger means (14) operative to move into and out of a main body (16) of the handle and being operative to move the gripping means to grip an object, the trigger means being provided with visual indication

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means indicating a defined intermediate position of the trigger means (i.e the amount of trigger material left outside the stationary portion of the handle), from which the subject-matter of claim 14 differs in that the visual indicator comprises a change in surface texture at a defined intermediate position, said surface texture change being dimensioned such that the clearance between the trigger means and said main body portion is minimal, thereby removing the possibility of snagging surgical gloves on movement of the trigger.

- 4.2 The problem to be solved by the applicator of claim 14 can be regarded as to provide an applicator with visual indicator means avoiding at the same time that surgical gloves are damaged by being caught between the trigger and the recess in the handle after a predetermined trigger position (corresponding to the user's fingers being more and more flexed while pulling the trigger to its final position, which provokes wrinkles in the gloves).
- 4.2 The available prior art is silent to the mention of this problem and the above solution, therefore the subject-matter of claim 14 is also considered to be inventive.